

Amendments to the Claims

Please amend the claims as follows, without prejudice or disclaimer. This claim listing replaces all previous claim listings.

1. (Currently amended) A culture medium for culturing a strain of *Corynebacterium diphtheriae* to produce a level of diphtheria toxin or an analog thereof wherein the medium is substantially free of animal-derived products and comprises: ~~a.~~ water; ~~b.~~ a carbohydrate source; ~~and~~ a nitrogen source; ~~c.~~ and a number of free amino acids in an initial concentration wherein the initial concentration of each free amino acid is not limiting for the level of production of the diphtheria toxin or the analog thereof.
2. (Originally filed) The culture medium of claim 1 comprising all naturally occurring amino acids.
3. (Originally filed) The culture medium of claim 1 wherein the carbohydrate source comprises maltose.
4. (Originally filed) The culture medium of claim 1 substantially free of glucose.
5. (Originally filed) The medium of claim 1 wherein the nitrogen source comprises yeast extract.
6. (Currently amended) The culture medium of claim 1 ~~or 2 or 3 or 4 or 5~~ wherein the medium is devoid of animal-derived products.
7. (Originally filed) A medium for *Corynebacterium diphtheriae* comprising: a carbohydrate source and a nitrogen source and an additive system that comprises at least four free amino acids being each in an amount sufficient to promote a level of diphtheria toxin or an analog thereof production by *Corynebacterium diphtheriae* wherein the medium is substantially free of animal-derived products.
8. (Originally filed) The culture medium of claim 7 comprising all naturally occurring amino acids.
9. (Originally filed) The medium of claim 7, wherein the carbohydrate source is maltose.
10. (Originally filed) The medium of claim 7, wherein the nitrogen source is yeast extract.

11. (Currently amended) The medium of claim 7 ~~or 8 or 9~~ wherein amino acid concentrations are in the range from about to 0.5 grams to about 1 gram per litre of the medium.
12. (Currently Amended) The ~~culture~~ medium of claim 7 ~~or 8 or 9 or 10 or 11~~ wherein the medium is devoid of animal-derived products.
13. (Currently Amended) A method for the production of diphtheria toxin or an analog thereof comprising the steps of: culturing a strain of *C. diphtheriae* in a culture medium under conditions that allow production of diphtheria toxin, wherein the culture medium is ~~substantially~~ substantially free of animal-derived products and comprises: ~~comprises~~ water; ~~a~~ a carbohydrate source; ~~and~~ a nitrogen source; ~~b~~ and a number of free amino acids in an initial concentration wherein the initial concentration of each free amino acid is not limiting for the level of production of the diphtheria toxin or the analog thereof.
14. (Originally filed) The method of claim 13, wherein the culture medium comprises all naturally occurring amino acids.
15. (Originally filed) The method of claim 13, wherein the carbohydrate source comprises maltose.
16. (Originally filed) The method of claim 13, wherein the culture medium is substantially free of glucose.
17. (Originally filed) The method of claim 13, wherein the nitrogen source comprises yeast extract.
18. (Originally filed) The method of claim 13 wherein the *C. diphtheriae* strain is grown until stationary phase.
19. (Originally filed) The method of claim 13 wherein a production of at least 100 Lf/mL of diphtheria toxin or analog thereof is obtained.
20. (Currently amended) The method of claim ~~10~~ 13 further comprising a step of recovering the diphtheria toxin or analog thereof to provide a recovered diphtheria toxin or analog thereof.
21. (Originally filed) The method of claim 17 further comprising a step of purifying the recovered diphtheria toxin or analog thereof to provide a purified diphtheria toxin or analog thereof.

22. (Originally filed) The method of claim 17 or 18 further comprising a step of detoxifying the recovered or purified diphtheria toxin or analog thereof to provide a diphtheria toxoid or analog thereof.

23. (Currently amended) The method of claim 19 further comprising formulating the diphtheria toxoid or analog thereof as a vaccine for immunizing a host ~~against disease~~ against disease caused by infection by *C. diphtheriae*.

24. (Currently amended) The method of ~~any one of claims~~ claim 13-23 wherein the medium is devoid of animal-derived products.

25. (Originally filed) A method of immunizing a host against disease caused by infection by *C. diphtheriae* comprising administering the vaccine of claim 23 to the host.

26. (Currently Amended) The use of the vaccine of claim 23 for immunizing a host ~~against disease~~ against disease caused by infection by *C. diphtheriae*.

27. (Originally filed) The use of the diphtheria toxoid or analog thereof of claim 22 in the preparation of a medicament for immunizing a host ~~against disease~~ against disease caused by infection by *C. diphtheriae*.

28. (Currently amended) A composition comprising a *C. diphtheriae* strain and a culture medium for producing diphtheria toxin or analog thereof wherein the medium is substantially substantially free of animal derived products and comprises wherein the culture medium is substantially substantially free of animal-derived products and ~~comprises~~ comprises: a—water; b—a carbohydrate source; and a nitrogen source; e—and a number of free amino acids in an initial concentration wherein the initial concentration of each free amino acid is not limiting for the level of production of the diphtheria toxin or the analog thereof.

29. (Currently amended) The composition of method of claim ~~24~~ 28, wherein the culture medium comprises all naturally occurring amino acids.

30. (Currently amended) The composition of method of claim ~~24~~ 28, wherein the carbohydrate source comprises maltose.

31. (Currently amended) The composition of claim ~~24~~ 28, wherein the culture medium is substantially free of glucose.

32. (Currently amended) The composition of method of claim ~~24~~ 28, wherein the nitrogen source comprises yeast extract.

33. (Currently amended) The culture medium of claim ~~28 21 or 22 or 22 or 23 or 24 or 25~~ wherein the medium is devoid of animal-derived products.

34. (Originally filed) A method for producing diphtheria toxin or an analog thereof comprising growing a culture of *Corynebacterium diphtheriae* in a medium and providing at least one selected amino acid to the culture to prevent concentrations of the selected amino acids being limiting for toxin production wherein the medium is substantially free of animal-derived products.

35. (Currently amended) The method of claim + 34 wherein the medium further comprises a yeast extract.

36. (Currently amended) The method of claim 4 35 wherein the yeast extract is present at a concentration of about 3g/L concentration of amino acids.

37. In a culturing method of *Corynebacterium diphtheriae* in a medium containing amino acids for producing a level of production of diphtheria toxin or an analog thereof and in which at least one selected amino acid is depleted during the culturing and limits the level of production of the diphtheria toxin or the analog thereof, the improvement comprising an exogenous addition of an additional amount of the at least one selected amino acid during said culturing and wherein the at least one selected amino acid is not limiting for the level of production of the diphtheria toxin or the analog thereof.

38. (Currently amended) The method of claim ~~33~~ 37 wherein the at least one selected amino acid is selected from the group consisting of Glu, Asn, Ser, His, Gly, Thr, Met, Trp, and Isoleucine.

39. (Currently amended) The method of claim ~~33~~ 37, wherein the medium comprises a yeast extract.

40. (Currently amended) The method of claim ~~35~~ 39 wherein the yeast extract is present at a concentration of about 3g/L.

41. (New) The culture medium of claim 2 wherein the medium is devoid of animal-derived products.

42. (New) The culture medium of claim 3 wherein the medium is devoid of animal-derived products.

43. (New) The culture medium of claim 4 wherein the medium is devoid of animal-derived products.

44. (New) The culture medium of claim 5 wherein the medium is devoid of animal-derived products.

45. (New) The medium of claim 8 wherein amino acid concentrations are in the range from about to 0.5 grams to about 1 gram per litre of the medium.

46. (New) The medium of claim 9 wherein amino acid concentrations are in the range from about to 0.5 grams to about 1 gram per litre of the medium.

47. (New) The medium of claim 10 wherein amino acid concentrations are in the range from about to 0.5 grams to about 1 gram per litre of the medium.

48. (New) The medium of claim 8 wherein the medium is devoid of animal-derived products.

49. (New) The medium of claim 9 wherein the medium is devoid of animal-derived products.

50. (New) The medium of claim 10 wherein the medium is devoid of animal-derived products.

51. (New) The medium of claim 11 wherein the medium is devoid of animal-derived products.

52. (New) The method of claim 14 wherein the medium is devoid of animal-derived products.

53. (New) The method of claim 15 wherein the medium is devoid of animal-derived products.

54. (New) The method of claim 16 wherein the medium is devoid of animal-derived products.

55. (New) The method of claim 17 wherein the medium is devoid of animal-derived products.

56. (New) The method of claim 18 wherein the medium is devoid of animal-derived products.

57. (New) The method of claim 19 wherein the medium is devoid of animal-derived products.

58. (New) The method of claim 20 wherein the medium is devoid of animal-derived products.

59. (New) The method of claim 21 wherein the medium is devoid of animal-derived products.
60. (New) The method of claim 22 wherein the medium is devoid of animal-derived products.
61. (New) The method of claim 23 wherein the medium is devoid of animal-derived products.
62. (New) The culture medium of claim 29 wherein the medium is devoid of animal-derived products.
63. (New) The culture medium of claim 30 wherein the medium is devoid of animal-derived products.
64. (New) The culture medium of claim 31 wherein the medium is devoid of animal-derived products.
65. (New) The culture medium of claim 32 wherein the medium is devoid of animal-derived products.